510(k) Summary Pursuant to 21 CFR 807.92

General Company Information

Company Name:	Olsen Medical®
Company Address:	3230 Commerce Center Place Louisville, Kentucky 40211
Company Telephone:	(502) 772-4280
Contact:	Dalene T. Binkley
Contact Address:	1927 N. Arthur Drive Columbia City, Indiana 46725 (260) 244-4189
Date:	October 7, 2013
Device Trade Name:	Olsen Medical Bipolar and Monopolar Forceps (Single and Multiple-Use)
Common Name:	Single Use Bipolar and Monopolar Forceps; Multiple-Use Bipolar and Monopolar Forceps
Classification Name and Reference:	GEI – 878.4400, Electrosurgical cutting and coagulation device and accessories
Predicate Device:	Bipolar Forceps: *Dermacare (now Olsen Medical) Disposable Bipolar Cord and Bipolar Forcep,* K884656, cleared November 25, 1988 *Olsen Medical Midas Touch Bipolar Forceps,* K982705, cleared September 8, 1998 *Stryker Bipolar Forceps*, K093108, cleared June 22, 2010

Monopolar Forceps:

Boston Surgical Products Reusable Monopolar Forceps, K950877, cleared March 9, 1995

Device Description:

OLSEN Medical® Electrosurgical Monopolar and Bipolar Forceps have been designed as active electrosurgical instruments to grasp, manipulate, cut or coagulate selected soft tissue. These stainless steel forceps are connected through a suitable active electrosurgical cable (bipolar or monopolar) to the specified output terminal of an electrosurgical generator. The bipolar forceps are intended for use with a maximum voltage of 500 volts while the monopolar forceps have a maximum voltage of 2000 volts. The forceps are offered either as single (disposable) or multiple-use (reuseable).

Intended Use:

The **OLSEN Medical Electrosurgical Monopolar and Bipolar Forceps** are intended to be used as active electrosurgical devices where monopolar or bipolar electrosurgical cutting and coagulation is desired during surgery and are intended to grasp, manipulate cut or coagulate selected soft tissue.

Comparison to Predicate Device:

The proposed Olsen Bipolar and Monopolar Forceps is similar in design as its predicates. The Olsen Forceps are sterilized using equivalent materials and processes as its predicates. The subject devices also have the same intended use and performance characteristics as their predicates. No new technological characteristics were introduced and as such, the proposed forceps do not raise new types of safety and effectiveness issues as compared to the predicates.

Testing and Technological Characteristics:

The Olsen Medical Bipolar and Monopolar Forceps are active electrosurgical devices that provide an electrical current that is fired through the tips of the forceps. The devices are hand-held and provided sterile for the single use forceps and non-sterile for the multiple use forceps. The forceps connect to a corresponding power cord (bipolar or monopolar).

The following testing was conducted with successful outcome to establish device safety and equivalence:

- IEC 60601-2-2 Medical Electrical Equipment/Part 2-2: Particular Requirements for Safety of High Frequency Surgical Equipment
- ANSI/AAMI/ISO 11137-2:2006: Sterilization of Health Care Products - Radiation - Part 2: Establishing the sterilization dose
- ISO 10993: Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ANSI/AAMI HF18-1993 American National Standard for Electrosurgical Devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Olsen Medical
% Ms. Dalene T. Binkley
FDC Services, LLC
1927 N. Arthur Drive
Columbia City, Indiana 46725

December 6, 2013

Re: K130669
Trade/Device Name: Olsen Medical® Bipolar and Monopolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 7, 2013
Received: October 11, 2013

Dear Ms. Binkley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K130669

510(k) Number (if Known):

Device Name: Device Name: Olsen Medical® Bipolar and Monopolar Forceps

Indications For Use: The **OLSEN Medical Electrosurgical Monopolar and Bipolar Forceps** are intended to be used as active electrosurgical devices where monopolar or bipolar electrosurgical cutting and coagulation is desired during surgery and are intended to grasp, manipulate cut or coagulate selected soft tissue.

Prescription Use: X OR Over-The-Counter Use:_____
(Part 21 CFR 807.109)

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A Digitally signed by Long H. Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=13003649056 Date: 2013.12.05 14:01:55 -05'00' for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K130669